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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,313	04/06/2001	Oswaldo da Costa e Silva	16313-0032	6571

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,313	E SILVA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,9</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-10 and 14-20, and Invention I, SEQ ID NOS: 22 and 35 (MPK-3), in Paper No. 11 is acknowledged. The traversal is on the ground(s) that examination of the thirteen groups of sequences (A-M) would not be an undue burden because of their close technological relationship, because the Examiner has not provided evidence that a search of all the PKSRP proteins and nucleic acids would be burdensome, and because according to The Official Gazette Notice of November 19, 1996, a reasonable number of sequences may be claimed in a single application, and according to MPEP 803.04 ten sequences are considered a reasonable number. Alternatively the traversal is on the ground(s) that examination of four sequences, MPK-2, MPK-3, MPK-4 and MPK-5 would not be an undue burden because of their close technological relationship.

This is not found persuasive because although the thirteen groups of sequences (A-M) may be related to one another, and although the four sequences MPK-2, MPK-3, MPK-4 and MPK-5 may be even more closely related to one another, each distinct nucleotide or amino acid sequence requires a separate search. Additionally, The Official Gazette Notice of November 19, 1996 is one that permits the examiner to waive restriction to no more than one invention. However, since 1996, databases and resource allocations at the PTO have changed, and the examination of more than one distinct sequence on the merits in the instant application would present a burden on PTO resources. Accordingly, claims 11-13 and 21-31 and the nonelected SEQ ID NOS are withdrawn from consideration as being drawn to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the third inventor did not sign the declaration.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed July 9, 2001 and June 17, 2002, Paper Nos. 3 and 9, are attached to the instant Office action.

Claim Objections

Claims 1-4, 14-15 and 17-20 are objected to because they recite the sequences of nonelected inventions. Appropriate correction is required.

Claims 9-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Appropriate correction is required.

Claim 15 is objected to because the acronym "PKSRP" is misspelled "PHSRP". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to transgenic plant cells transformed with a MAP Kinase-3 (MPK-3) Protein Kinase Stress-Related Protein (PKSRP) coding nucleic acid, and orthologs thereof. The claims are also drawn to a transgenic plant and seed, an isolated nucleic acid, and a method of producing a transgenic plant.

The specification describes fourteen isolated DNA molecules that encode different types of proteins homologous to various structurally and functionally distinct kinase proteins (pages 49-50 Table 1). One of these isolated DNA molecules, the elected nucleic acid of SEQ ID NO:22 isolated from *Physcomitrella patens*, encodes the protein of SEQ ID NO: 35 (MAP Kinase-3) which has homology to big MAP kinase 1c (page 50 Table 1), as well as homology to extensins and other proline-rich proteins (page 54 Table 10). Ten of these isolated DNA molecules improve drought stress tolerance when expressed in transgenic *Arabidopsis* plants, including the elected nucleic acid of SEQ ID NO:22 (page 68 Table 17). Six of these isolated DNA molecules improve freezing stress tolerance when expressed in transgenic *Arabidopsis* plants, including the elected nucleic acid of SEQ ID NO:22 (page 69 Table 18). This does not constitute a substantial portion of the genus that comprises MAP Kinase-3 Protein Kinase Stress-Related Protein coding nucleic acids and orthologs thereof which increase tolerance to an environmental stress when expressed in a transgenic plant cell. The claimed genus encompasses a multitude of different

nucleotide sequences and proteins, including those yet to be discovered. Furthermore, the recitation of "orthologs thereof" in the claims implies that MAP Kinase-3 Protein Kinase Stress-Related Protein orthologs exist, yet the specification does not describe the structure of any MAP Kinase-3 Protein Kinase Stress-Related Protein ortholog. The disclosure of fourteen isolated DNA molecules that encode different proteins homologous to various structurally and functionally distinct kinase proteins, ten of which improve drought stress tolerance when expressed in transgenic *Arabidopsis* plants, and six of which improve freezing stress tolerance when expressed in transgenic *Arabidopsis* plants, does not provide an adequate description of the claimed genera, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of MAP Kinase-3 Protein Kinase Stress-Related Protein coding nucleic acids (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-10 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant transformed with a nucleic acid of SEQ ID NO:22 encoding a polypeptide of SEQ ID NO:35, said plant exhibiting increased tolerance to drought and freezing stress, does not reasonably provide enablement for transgenic plants transformed with other MAP Kinase-3 Protein Kinase Stress-Related Protein coding nucleic acids, said plants exhibiting tolerance to all environmental stresses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to transgenic plant cells transformed with a MAP Kinase-3 (MPK-3) Protein Kinase Stress-Related Protein (PKSRP) coding nucleic acid and orthologs thereof, a

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MPK-3 nucleic acid encoding SEQ ID NO:35, a MPK-3 coding nucleic acid of SEQ ID NO:22, and a MPK-3 coding nucleic acid that hybridizes under stringent conditions to SEQ ID NO:22.

The claims are also drawn to a transgenic plant and seed, and a method of producing a transgenic plant.

The specification discloses the elected nucleic acid of SEQ ID NO:22 isolated from *Physcomitrella patens* that encodes a protein (MPK-3) of SEQ ID NO:35 having amino acid sequence homology to big MAP kinase 1c (page 50 Table 1), as well as to extensins and other proline-rich proteins (page 54 Table 10). The specification also discloses that expression of a nucleic acid of SEQ ID NO:22 in transgenic *Arabidopsis* increases the plant's tolerance to drought stress and freezing stress as compared to nontransformed control plants (pages 68-69, Tables 17 and 18).

While one of skill in the art could readily make transgenic plants expressing any polynucleotide encoding a polypeptide having homology to big MAP kinase 1c, it would require undue experimentation for one skilled in the art to determine which polynucleotide to express and at what level, because the ability of such a polynucleotide to confer stress tolerance in a transgenic plant is unpredictable. The specification does not provide sufficient guidance for one skilled in the art to determine which polynucleotide to express and at what level, because the specification teaches only one polynucleotide encoding a protein having homology to big MAP kinase 1c that can increase drought stress tolerance when expressed in a transgenic plant. Also, while one of skill in the art could readily make transgenic plants comprising any polynucleotide encoding a polypeptide having homology to big MAP kinase 1c, it would require undue experimentation for one skilled in the art to determine how to express such a polynucleotide in a manner that would increase tolerance to stresses other than drought or freezing, because the

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specification does not teach how to express a polynucleotide encoding a big MAP kinase 1c such that tolerance to stresses other than drought or freezing is increased, such as tolerance to salinity, water-logged or poorly aerated soils. Furthermore, the specification does not disclose the structure and function of any MPK-3 ortholog, and such orthologs cannot be predicted from Applicant's disclosure, as orthologs by definition have evolved to become "different" from each other. The specification does not provide sufficient guidance for one skilled in the art to identify, without undue experimentation, MPK-3 orthologs that could be used to practice the claimed invention. Additionally, the specification does not disclose the effect of expressing a polynucleotide encoding a polypeptide having homology to big MAP kinase 1c on environmental stress tolerance in any host cell type other than a plant cell. While one of skill in the art could readily transform other types of host cells, such as bacteria, yeast, mammalian, etc., and express any polynucleotide encoding a polypeptide having homology to big MAP kinase 1c, it would require undue experimentation for one skilled in the art to identify which type of host cell to transform, and how to express the polynucleotide in that cell such that environmental stress tolerance of the host cell is increased, because the ability of such a polynucleotide to confer stress tolerance in host cells other than plant cells is unpredictable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 14-15 and 17-20 are indefinite in the recitation of "Stress-Related Protein" or "PKSRP", because the relationship between stress and the protein is unclear. Does the protein alleviate stress, or is the protein expressed in response to stress?

Claims 1, 10 and 16-17 are indefinite in the recitation of "environmental stress". It is unclear what type of environmental stress the cell would have increased tolerance to, as a change in any environmental parameter may be a source of stress to a cell.

Claims 1 and 17 are indefinite in the recitation of "orthologs thereof". It is unclear what orthologs are intended, orthologs of CPK-2, or orthologs of all thirteen proteins? The metes and bounds of "ortholog" are unclear.

Claims 4, 15 and 20 are indefinite in the recitation of "hybridizes under stringent conditions". It is unclear what conditions would yield the claimed nucleic acid molecules, as those skilled in the art define stringency differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 8 is indefinite in the recitation of "forage crops", as a forage crops are not a plant.

Claims 9 and 10 are indefinite in the recitation of the indefinite article "a" before "plant cell". It is suggested that the claims be amended to recite the definite article "the" before "plant cell".

Claim 10 is indefinite in the recitation of "true breeding", as it is unclear how a seed would be "true breeding". Does the seed contain the nucleic acid of interest? Is the seed homozygous?

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 17 is missing the essential step of expressing a Protein Kinase Stress-Related

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Protein. In the absence of expression of a Protein Kinase Stress-Related Protein, the method of claim 17 will not result in the production of a transgenic plant with an increased tolerance to environmental stress.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 10 is drawn to seed, but is not limited to seed that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that plant. In addition, even though the claim recites that the seed is true breeding for an increased tolerance to an environmental stress, a native gene independent of the transgene introduced into the parent could confer such a trait, given that there is no indication that there would be any other distinguishable characteristics of the claimed seed, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the seed comprises the construct that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, 8, 9, 15, 16, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Seo et al. (The Plant Cell, Vol. 11, pages 289-298, February 1999).

The claims are drawn to transgenic dicotyledonous tobacco plants and plant cells transformed with a MAP Kinase-3 (MPK-3) Protein Kinase Stress-Related Protein (PKSRP) coding nucleic acid and orthologs thereof, including a PKSRP coding nucleic acid that hybridizes under stringent conditions to SEQ ID NO:22, wherein expression of the nucleic acid results in increased tolerance to an environmental stress. The claims are also drawn to an isolated PKSRP coding nucleic acid that that hybridizes under stringent conditions to SEQ ID NO:22, an isolated recombinant expression vector, and a method of producing a transgenic plant using a MAP Kinase-3 (MPK-3) Protein Kinase Stress-Related Protein (PKSRP) coding nucleic acid and orthologs thereof, including a PKSRP coding nucleic acid that hybridizes under stringent conditions to SEQ ID NO:22, wherein expression of the nucleic acid results in increased tolerance to an environmental stress.

Seo et al. teach transgenic dicotyledonous tobacco plants and plant cells transformed with a recombinant expression vector comprising a WIPK coding nucleic acid (page 293 Figure 5). Because WIPK is a MAP Kinase, WIPK is a MAP Kinase-3 ortholog. Because WIPK is a MAP Kinase, a WIPK coding nucleic acid would hybridize under "stringent conditions" to SEQ ID

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NO:22. Because expression of the WIPK coding nucleic acid results in increased levels of jasmonates as compared to nontransformed plants (page 294, Figure 6), expression of the WIPK coding nucleic acid inherently results in increased tolerance to the environmental stress of wounding, as jasmonates transcriptionally activate genes that encode proteinase inhibitors involved in healing injured tissues (page 289 column 1 first paragraph).

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
September 28, 2002

Phuong Bui
9/30/02
PHUONG T. BUI
PRIMARY EXAMINER